

Notice of Allowability

Application No.

10/648,786

Examiner

Claire M. Kaufman

Applicant(s)

NI ET AL.

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's response of 10/29/07 and telephone interview for the Ex's Amd't of 11/28/07.
2. ☒ The allowed claim(s) is/are 26-45, 48-58, 60-69 and 72-77.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material

5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Shannon A. Carroll on November 27, 2007.

The application has been amended as follows:

Please cancel the following claims: 46, 47, 59, 70 and 71.

Please replace claims 26, 48, 51 and 72 as follows:

Claim 26 (Currently amended). A method for treating cancer comprising administering to an individual therapeutically effective amounts of:

(a) a first therapeutic agent comprising an antibody which binds to a polypeptide selected from the group consisting of:

- (i) amino acids 1 to 468 of SEQ ID NO:2;
- (ii) amino acids 24 to 468 of SEQ ID NO:2;
- (iii) amino acids 24 to 238 of SEQ ID NO:2;
- (iv) the amino acid sequence of the full-length polypeptide encoded by the cDNA contained in ATCC Deposit No. 97853;
- (v) the amino acid sequence of the mature polypeptide encoded by the cDNA contained in ATCC Deposit No. 97853; and
- (vi) the amino acid sequence of the extracellular domain of the polypeptide encoded by the cDNA contained in ATCC Deposit No. 97853;

and

- (b) a second therapeutic agent selected from the group consisting of:
 - (i) TRAIL;
 - (ii) a tumor necrosis factor;

- ~~(iii)~~—a tumor necrosis factor blocking agent;
- ~~(iv)~~—an immunosuppressive agent;
- ~~(v)~~—an antibiotic;
- ~~(vi)~~—an anti-inflammatory agent;
- ~~(vii)~~—a chemotherapeutic agent; and
- ~~(viii)~~ iii) a cytokine.

Claim 48 (Currently Amended). The method of claim 26, wherein said second therapeutic agent is a cytokine selected from the group consisting of:

- (a) IL-2;
- ~~(b)~~—IL-3;
- ~~(c)~~—IL-4;
- ~~(d)~~—IL-5;
- ~~(e)~~—IL-6;
- ~~(f)~~—IL-7;
- ~~(g)~~—IL-10;
- ~~(h)~~ b) IL-12;
- ~~(i)~~—IL-13;
- ~~(j)~~ c) IL-15; and
- ~~(k)~~ d) IFN- γ .

Claim 51 (Currently amended). A composition comprising:

(a) a first therapeutic agent comprising an agonist antibody which binds to a polypeptide selected from the group consisting of:

- (i) amino acids 1 to 468 of SEQ ID NO:2, wherein said polypeptide is expressed on the surface of a cell;
- (ii) amino acids 24 to 468 of SEQ ID NO:2, wherein said polypeptide is expressed on the surface of a cell;

(iii) amino acids 24 to 238 of SEQ ID NO:2, wherein said polypeptide is expressed on the surface of a cell;

(iv) the amino acid sequence of the full-length polypeptide encoded by the cDNA contained in ATCC Deposit No. 97853, wherein said polypeptide is expressed on the surface of a cell;

(v) the amino acid sequence of the mature polypeptide encoded by the cDNA contained in ATCC Deposit No. 97853, wherein said polypeptide is expressed on the surface of a cell; and

(vi) the amino acid sequence of the extracellular domain of the polypeptide encoded by the cDNA contained in ATCC Deposit No. 97853, wherein said polypeptide is expressed on the surface of a cell;

and

(b) a second therapeutic agent selected from the group consisting of:

(i) TRAIL;

(ii) a tumor necrosis factor;

~~(iii) a tumor necrosis factor blocking agent;~~

~~(iv) an immunosuppressive agent;~~

~~(v) an antibiotic;~~

~~(vi) an anti-inflammatory agent;~~

~~(vii) a chemotherapeutic agent; and~~

~~(viii)~~ iii) a cytokine.

Claim 72 (Currently Amended). The composition of claim 51, wherein said second therapeutic agent is a cytokine selected from the group consisting of:

(a) IL-2;

~~(b) IL-3;~~

~~(c) IL-4;~~

~~(d) IL-5;~~

- (e) — IL-6;
- (f) — IL-7;
- (g) — IL-10;
- (h b) IL-12;
- (i) — IL-13;
- (j c) IL-15; and
- (k d) IFN- γ .

Terminal Disclaimer

The terminal disclaimers filed on 10/29/07 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 7,060,272, 6,943,020 or 6,461,823 have been reviewed and are accepted. The terminal disclaimers have been recorded.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: Through the examiner's search, additional species of second therapeutic agents were found to be allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571) 272-0873. Dr. Kaufman can generally be reached Monday, Tuesday, Thursday and Friday from 9:30AM to 2:30PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached at (571) 272-0835.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (571) 273-8300. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Claire Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

November 28, 2007



LORRAINE SPECTOR
PRIMARY EXAMINER